

Isofield CR+

Sterile 400mm (16")
Cleanroom Latex Gloves



PRODUCT INFO

GMP Grade A compatible
ISO Class 4 & 5 compatible
Sterile
Latex
Natural colour
Elbow length 400mm (16")
Ambidextrous
Textured palm & fingers
Beaded cuff
Protein level less than 50µg/g
Double-donnable

QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system
Processed in a NEBB certified ISO Class 5 Cleanroom
Physical properties comply with European medical glove standard EN455-2:2015

STERILIZATION

Gamma irradiation, Minimum 25 kGy

SHELF LIFE

Three (3) years from date of manufacture

STORAGE

Store in a dry, cool place (<40°C) away from direct sunlight. Do not expose open cartons to prolonged direct fluorescent light

PACKING

One pair per inner PE wallet,
One PE wallet per sealed PE pouch,
10 pouches per PE bag,
20 sealed PE bags per lined carton (200 pairs)

PRODUCT CODE		
REF 10040		
SMALL	6.0-6.5	10040S
MEDIUM	7.0-7.5	10040M
LARGE	8.0- 8.5	10040L
XLARGE	9.0	10040XL



PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.20	7.87	EN455-2:2015
Palm	0.17	6.69	
Cuff	0.11	4.33	

* +/- 0.02mm

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	390mm	400mm	EN ISO 21420 :2020

STRENGTH PROPERTIES	FORCE AT BREAK	TEST METHOD
Throughout shelf life	≥ 6.0 N	EN455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	0.65 - Level 3 of 3	EN374-2:2016

CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm ²)	1200	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm ²)	TEST METHOD
Fluoride (F)	0.005	IEST-RP-CC005.4
Chloride (Cl)	0.750	
Nitrite (NO ₂)	0.042	
Bromide (Br)	0.043	
Nitrate (NO ₃)	0.410	
Phosphate (PO ₄)	0.044	
Sulphate (SO ₄)	0.120	
Lithium (Li)	0.006	
Sodium (Na)	0.040	
Ammonium (NH ₄)	0.110	
Potassium (K)	0.050	
Calcium (Ca)	0.510	
Magnesium (Mg)	0.010	
Zinc (Zn)	0.536	

* ND = Not Detected